

REMARKS

Claims 1 and 2 are amended, claims 7-20 are canceled, and claims 1-6 are pending in the application.

The examiner has maintained his rejection of all pending claims (1-20) pursuant to 35 U.S.C. §112, (first paragraph) asserting that the patent application's "specification does not reasonably provide enablement for identifying any change in the body of a human being caused by any physiological or pathological condition." The Examiner argues that the "specification provides no guidance regarding methods for identification of any other change in the body of a human being caused by other physiological or pathological condition and no guidance has been provided to detect DNA [complex] patterns in male patients." The examiner concludes that it is "highly unpredictable whether or what other diseases would be detected by identifying DNA [complex patterns] extracted from blood". Claims 1 and 2 are herein amended to reflect only the process for preparing a blood sample which is set forth in exacting detail in the present specification. The steps of determining the sex of a fetus, or of detecting a change in the body of a human being caused by a physiological or pathological condition have been eliminated along with all associated language. Since the specification makes it abundantly clear how to perform the method of preparing a blood sample, and since one skilled in the art would have no difficulty in following the method steps, it is believed that claims 1 and 2 and depending claims 3-6 are now fully enabled.

In light of the above amendments and remarks, the claims are believed to avoid all the rejections set forth in the Official Action. Thus, claims 1-6 are in condition for allowance. A Notice to this effect is respectfully requested.

Respectfully submitted,

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## APPENDIX A: Redlined Claims

1.(Twice amended) A method of [determining the sex of a fetus] processing human blood samples to form a DNA complex strand pattern, comprising the steps of:

- a. mixing a sample of blood [from a pregnant woman] containing plasma and blood cells with an anticoagulant to form an anti-coagulated blood mixture;
- b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;
- c. preparing a first blood cell mixture in accordance with the following steps:
  - i. preparing approximately one (1) volume of Tris-buffer;
  - ii. adding approximately a half ( $\frac{1}{2}$ ) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and
  - iii. adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;
- d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;
- e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half ( $\frac{1}{2}$ ) volume of chloroform and approximately a half ( $\frac{1}{2}$ ) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;
- f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;
- g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;
- h. placing an acid alcohol sample consisting of approximately twelve and a half ( $12\frac{1}{2}$ ) volumes of freshly made 20% acid alcohol on a slide; and
- i. adding a blood cell sample consisting of approximately one fifth ( $\frac{1}{5}$ ) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide[]; and
- j. determining that the sex of the fetus is female if the shape of the strand pattern is

approximately circular or polygonal, or that the sex of the fetus is male if the shape of the strand pattern is generally linear or generally linear in combination with at least one elongated ring].

2.(Twice amended) A method of [determining the sex of a fetus] processing human blood samples to form a DNA complex strand pattern, comprising the steps of:

- a. mixing a sample of blood [from a pregnant woman] containing plasma and blood cells with an anticoagulant to form an anti-coagulated blood mixture;
- b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;
- c. preparing a first blood cell mixture in accordance with the following steps:
  - i. preparing approximately 5 ml of Tris-buffer;
  - ii. adding approximately 2.5 ml of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 ml of Tris-buffer to produce a buffer diluted phenol; and
  - iii. adding approximately 10 ml of the blood cells to the buffer diluted phenol;
- d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;
- e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 ml of chloroform and approximately 2.5 ml of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;
- f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;
- g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;
- h. placing an acid alcohol sample consisting of approximately 25 ml of freshly made 20% acid alcohol on a slide;
- i. adding a blood cell sample consisting of approximately 1.0 ml of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide[; and
- j. determining that the sex of the fetus is female if the shape of the strand pattern is

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approximately circular or polygonal, or that the sex of the fetus is male if the shape of the strand pattern is generally linear or generally linear in combination with at least one elongated ring].